

Health ABC GWAS Analysis Proposal and Publications Guidelines

A. Goals

A.1. To encourage high quality publications and presentations produced in a timely fashion.

A.2. To encourage broad participation by Health ABC investigators and collaborators in publications and presentations.

A.3. To create an electronic tracking log that Health ABC investigators and collaborators can refer to for the status of genetics analysis using Health ABC GWAS data.

B. Scope of the guidelines

B.1. These guidelines apply to investigators affiliated with the Health ABC study and to those without an affiliation with Health ABC who are proposing an analysis, publication, or report that utilizes data from the Genome Wide Association Study (GWAS) or other SNP data from the Health ABC Study.

B.2. These guidelines apply to analysis of the Health ABC GWAS data or Health ABC SNP data by any investigator or analyst who wishes to present or publish the results of their analysis in the form of papers (including methodology and validation papers), abstracts/extended abstracts, oral and poster presentations, letters to the editor, and meeting proceedings or include results in the background, significance, rationale or other sections of a funding proposal.

B.3. These policies remain in effect after formal funding for the study ends.

C. GWAS Publications Committee

C.1. The Health ABC GWAS Publications Committee will be composed of volunteer reviewers (many of whom will be members of the Health ABC GWAS Working Group), and may be subject to approval by a majority vote of the Health ABC Executive Committee. The GWAS Publications Committee will be composed of one chair and up to six rotating reviewers, with the reviewers serving for a period of three consecutive months. Analysis proposals will be assigned to two of the six reviewers by the Publications Coordinator. Reviewers can serve on the Committee for more than one review cycle per year, but must rotate off the Committee for one review cycle before returning.

D. Types of publications

D.1. The guidelines encompass eight different types of publications:

D.1.1. Scientific manuscripts reporting Health ABC GWAS data.

D.1.2. Scientific manuscripts in which Health ABC is part of a multi-study consortium and thus contributing to a meta-analysis.

D.1.3. Scientific manuscripts in which Health ABC serves as a replication cohort.

D.1.4. Scientific manuscripts reporting data collected from sub-groups of the Health ABC cohort.

D.1.5. Methodology/validation papers.

D.1.6. Abstracts, meeting proceedings/extended abstracts, and presentations (oral and poster) submitted to meetings.

D.1.7. Letters to the editor.

D.1.8. Background, significance, rationale or other sections within funding proposals.

E. Authorship

E.1. Authors should participate in the writing of the paper in accordance with the International Committee of Medical Journal Editors guidelines (N Engl J Med 1991;324:424-8).

E.2. Non-Health ABC scientists and fellows may serve as first authors on papers and abstracts, but at least one senior Health ABC investigator must serve as a co-author and "sponsor" of the project. For purposes of these guidelines, senior investigators are listed in Addendum I.

E.3. Health ABC authors on consortia publications or multi-study collaborative analyses must include at least three Health ABC investigators, with one of the three being a senior Health ABC investigator listed in Appendix 1, and another from Dr. Yongmei Liu's laboratory at Wake Forest University Health Sciences (Dr. Liu is the Principal Investigator of the NIA grant that funded the *Genome-Wide Association Study*).

E.4. Authorship in genetics consortia or in collaborations across multiple studies does not require inclusion of authors from each of the Health ABC sites.

F. Official study name, required acknowledgements, and recommended terminology

F.1. The official name of the study for scientific purposes is the “Health, Aging, and Body Composition Study.” When referring to the Health ABC Study in the text of an abstract or paper, refer to it as the “Health, Aging, and Body Composition Study.” If space is an issue, refer to the study as the “Health ABC Study.”

F.2. Required Acknowledgements. All papers, abstracts, posters, and oral presentations must include the following:

a. *“This research was supported by NIA contracts N01AG62101, N01AG62103, and N01AG62106. The genome-wide association study was funded by NIA grant 1R01AG032098-01A1 to Wake Forest University Health Sciences and genotyping services were provided by the Center for Inherited Disease Research (CIDR). CIDR is fully funded through a federal contract from the National Institutes of Health to The Johns Hopkins University, contract number HHSN268200782096C.”*

b. Health ABC publications using ancillary study data should acknowledge the grant or contract number of the ancillary study.

c. Manuscripts which include co-authors from the NIA must include the following acknowledgment statement:

“This research was supported in part by the Intramural Research Program of the NIH, National Institute on Aging.”

d. Use of data from the DXA validation studies, Health ABC QDR 4500, and whole body phantoms should acknowledge support from Hologic, Inc.

G. Availability and analysis of data

G.1. GWAS data will not be widely distributed. Five sites have been approved by the Health ABC Executive Committee to house this data:

- Dr. Liu’s laboratory at Wake Forest University
- Dr. Kammerer’s laboratory at University of Pittsburgh
- Dr. Satterfield’s department at University of Tennessee
- Health ABC Coordinating Center at University of California, San Francisco
- NIA Laboratory of Epidemiology, Demography, and Biometry (Project Office)

G.2. GWAS analysis must be performed at one of the approved sites and must be coordinated by the lead author of the analysis plan and manuscript.

G.3. Investigators who cannot work with or at one of the approved sites have the option of requesting access through the NIA to an “external network drive” by which they could perform limited analysis.

H. Analysis Plans

H.1. Submitting Analysis Plans

H.1.1. All investigators planning projects or publications utilizing the Health ABC GWAS data must submit an analysis plan to the Health ABC GWAS Publications Committee for approval.

H.1.2. Analysis plans should be e-mailed to a central mailbox (HABCGWASPublications@psg.ucsf.edu) at the Health ABC Coordinating Center at the University of California, San Francisco. The analysis plan must include:

- a. The name of the first author.
- b. The name of the sponsoring Health ABC investigator (if necessary) and/or senior co-author (Health ABC investigator), who will also serve as the manuscript reviewer.
- c. Contact information for first author, including telephone number, fax number, and e-mail address.
- d. Working title of analysis plan.
- e. Provisional list of co-authors.
- f. Research question(s) and/or hypothesis.
- g. A one-paragraph background and rationale for addressing the research question or hypothesis in Health ABC.
- h. Definition of the phenotype using Health ABC variable names and referencing Health ABC datasets; the algorithm for defining cases and controls, and if appropriate, exclusion criteria; any other variables/covariates that will be used in analysis.
- i. Definition of secondary phenotypes that may also be analyzed.
- j. Indication of whether African-American (black) participants, European-American (white) participants, or both will be included in the analysis.
- k. The site that will be responsible for analyzing the data.
- l. Data submission deadline for consortia or other collaborations.
- m. Deadlines for submission of abstracts (if applicable).
- n. Indication of whether consortia involvement requires signed agreement from an official Health ABC representative.

H.1.3. In general, each analysis plan should be designed to result in a single manuscript. In the case of consortium collaborations, the phenotype(s) defined in a single analysis plan may result in more than one publication.

H.1.4. If the objectives of an analysis plan evolve and deviate substantially from the original plan, the first author is responsible for submitting an amended analysis plan.

H.1.5. Analysis plans cannot combine analysis of SNPs (single nucleotide polymorphism) and CNVs (Copy Number Variants). If analysis is planned on both SNPs and CNVs, separate analysis plans must be submitted.

H.2. Review and Approval of Analysis Plans.

The process is as follows:

H.2.1. Analysis plans must be submitted to the GWAS Publications Committee (HABCGWASPublications@psg.ucsf.edu) a minimum of 4 weeks prior to an abstract deadline to allow for time for review and possible revision of the analysis plan and/or abstract.

H.2.2. Once an analysis plan is received by the Publications Coordinator and sent out to reviewers, it will be listed on the Health ABC Analysis Plan Tracking Log on the Health ABC website, with a status of “under review.” GWAS analysis plans will be distinguished with a notation in both the Title column and Comments column in the Analysis Plan Tracking Log. The Analysis Proposal Tracking Log can be searched for GWAS proposals by entering “GWAS” into the Keyword search field.

H.2.3. Analysis plans will be distributed to two reviewers serving on the GWAS Publications Committee for review and approval. They will evaluate overlap with existing proposals and may recommend additional co-authors. Analysis plans may also be distributed to members of the Executive Committee to keep them abreast of GWAS analyses proposed and consortia involvement.

H.2.4. Reviewers will have 10 working days to review a submitted analysis plan and send their approval status and comments to the Publications Coordinator using the Health ABC GWAS Publications mailbox (HABCGWASPublications@psg.ucsf.edu) at the Coordinating Center.

H.2.5. Approval status and reviewers feedback will be sent to the first author by e-mail from the Health ABC Coordinating Center.

H.2.6. If an analysis plan is not approved, the first author may be requested to revise and resubmit the plan. If necessary, final approval of an analysis plan will require a majority vote of the Executive Committee.

H.2.7. After approval by the Health ABC GWAS Publications Committee, analysis plans will be posted on the secure area of the Health ABC web site.

H.2.8. Any investigator wishing to join the writing group should contact the first author. The Publications Coordinator will depend on the first author to provide updates regarding members of the writing group.

H.3. Expiration

H.3.1. Analysis plans expire six (6) months from the date of approval of the analysis plan. If the Publications Coordinator has not received a draft of an abstract or manuscript within 6 months, the GWAS Publications Committee may label the plan expired and propose that other investigators take over work on the phenotype.

H.3.2. Plans may also expire and authorship potentially reassigned if a manuscript has not been submitted for publication within 12 months from the date of approval of the analysis plan. Requests for extensions will be managed by the GWAS Publications Committee.

I. Review and approval of abstracts and presentations

I.1. Abstracts and presentations must have approved analysis plans BEFORE the abstract is submitted to the GWAS Publications Committee for review. Analysis plans must be submitted to the GWAS Publications Committee a minimum of 4 weeks prior to an abstract deadline to allow time for review and possible revision of the plan and/or abstract.

I.2. Abstracts must be reviewed and approved by all co-authors prior to submission to the GWAS Publications Committee.

I.3. Abstracts must be approved by the GWAS Publications Committee prior to submission to a meeting.

I.4. The abstract approval process is as follows:

I.4.1. At least seven working days prior to the abstract deadline, a draft of the abstract must be submitted to GWAS Publications Committee using the Health ABC GWAS publications mailbox (HABCGWASPublications@psg.ucsf.edu) with the word "ABSTRACT" in the e-mail subject line. The abstract will be distributed to two reviewers for approval.

I.4.2. An alternative and expedited process can be utilized for the review and approval of abstracts. Co-authors who are members of either the Health ABC Executive Committee or GWAS Publications Committee can indicate their approval at the time the abstract is submitted to the Publications Coordinator. The first author is responsible for having the co-author/reviewer sign the Abstract/Presentations Approval Form (available on the Health ABC website) and for e-mailing the form to the GWAS publications mailbox (HABCGWASPublications@psg.ucsf.edu) prior to the submission deadline for the abstract.

I.4.3. Approval or disapproval of the abstract and any accompanying comments will be sent by e-mail from the Health ABC Coordinating Center to the first author.

I.5. After approval by the Health ABC GWAS Publications Committee, the Publications Coordinator at the Health ABC Coordinating Center will post the final version of the abstract on the secure area of the Health ABC website.

I.6. Final versions of oral and poster presentations must be submitted to the GWAS Publication Committee using the Health ABC GWAS publications mailbox (HABCGWASPublications@psg.ucsf.edu) for approval at least seven days prior to their presentation at a scientific meeting. The review process (including the expedited process) will be handled in the same manner as for abstracts. No formal review is required for presentations (oral or poster) to national or international meetings if the first author and presenter is a paid Health ABC investigator.

J. Review and approval of papers/manuscripts

J.1. Manuscripts must have an approved analysis plan before they are submitted to the Committee for review.

J.2. Manuscripts must be reviewed by all co-authors prior to submission to the GWAS Publications Committee. It is the first author's responsibility to manage this step. The first author must send the final version of their manuscript to their writing group prior to submitting it to the GWAS Publications Committee for final approval.

J.3. Manuscripts must be approved by an internal reviewer, which should usually be the senior Health ABC co-author, with final approval by the GWAS Publications Committee prior to submission for publication.

J.4. Manuscripts must also receive clearance from the NIA prior to submission for publication if an NIA investigator is included as a co-author.

J.5. Manuscript approval process is as follows:

J.5.1. The first author is responsible for sending the manuscript to the senior Health ABC co-author reviewer for detailed comments.

J.5.2. The first author must complete a GWAS Manuscript Approval Form (available on the Health ABC website) confirming that all co-authors have had the opportunity to review the manuscript and provide comments. For consortium-based papers, the first author, last author, and all Health ABC co-authors, including the senior Health ABC co-author reviewer, must also sign the GWAS Manuscript Approval Form confirming that they approve the manuscript for submission to the GWAS Publications Committee. The reviewer may withhold approval pending revision. Once the required signatures are obtained, the GWAS Manuscript Approval Forms and the manuscript should be sent electronically to the GWAS Publications Committee mailbox (HABCGWASPublications@psg.ucsf.edu).

J5.3. If the reviewer disapproves of the submission of a manuscript to the GWAS Publications Committee after a good faith effort on the part of the authors to respond to concerns, the Health ABC Executive Committee will approve or withdraw submission of the manuscript by majority vote of all members.

J5.4. The Publications Coordinator will review the submitted forms and manuscript (confirming required acknowledgements, authorship, etc). A memo from the GWAS Publications Committee (generated by the Publications Coordinator) with the approval status of the manuscript will be e-mailed to the first author, last author, and senior Health ABC co-author.

J5.5. The Publications Coordinator will forward the approved manuscript to the NIA Project Office for clearance submission.

J5.6. The NIA Project Office will notify the Publications Coordinator of the NIA clearance decision within 2 to 3 weeks of receipt of the manuscript. The Publications Coordinator will generate and e-mail a memo to the first author, last author, and senior Health ABC co-author concerning NIA clearance decision. A manuscript can be submitted for publication once the first author has been notified that the NIA has cleared it for publication.

J5.7. The first author is responsible for sending an electronic copy of the final version of the manuscript (in Microsoft Word format) to the Publications Coordinator (HABCGWASPublications@psg.ucsf.edu).

J5.8. The first author should notify the Publications Coordinator when their manuscript is accepted for publication.

J5.9. The first author is required to submit final peer-reviewed journal manuscripts that result from NIH funded research to the digital archive PubMed Central (<http://www.pubmedcentral.nih.gov/>) within 12 months of acceptance for publication.

J5.10. The first author is responsible for sending any algorithms or statistical programming code for derived variables (also known as calculated variables) constructed specifically for the analysis in the paper to the GWAS Publications Committee mailbox (HABCGWASPublications@psg.ucsf.edu).

K. Miscellaneous

K.1. Meeting Proceedings and Extended Abstracts that are nearly identical to or minimally expand on an approved abstract do not need to be submitted to the GWAS Publications Committee for review prior to submission for publication. These should be reviewed by all co-authors prior to submission.

K.2. Meeting Proceedings and Extended Abstracts that significantly expand an approved abstract must be submitted to the GWAS Publications Committee for review prior to submission for publication. New analyses and results not included in the abstract and substantial additional detail about methods are examples of significant expansion. The approval process will be handled in the same manner as for abstracts.

K.3. In order not to jeopardize the publication of the complete manuscript in a peer-reviewed journal, investigators are encouraged to take a “minimalist” approach when drafting Meeting Proceedings and Expanded Abstracts. The content should closely mirror the abstract; the analyses and results should be presented with the same level of detail as the abstract. Expanding the background and discussion sections is a good alternative to expanding the methods and results section. Authors should feel free to provide half as much text as requested for the Meeting Proceedings and Expanded Abstract.

L. Archives

The Health ABC Coordinating Center will maintain an electronic archive of all Health ABC publications. Electronic copies of the final version of all papers and abstracts, including local papers, will be posted on the secure area of the Health ABC web site.

Appendix 1. Health ABC Senior Investigators

Name

Cummings, Steve
Harris, Tamara
Kritchevsky, Steve
Nevitt, Michael
Newman, Anne
Satterfield, Suzanne
Simonsick, Eleanor
Strotmeyer, Elsa
Tylavsky, Fran